REMARKS

In reply to the Office Action dated March 5, 2004, claims 23-24 and 35-36 are currently under examination in the Application. By the above amendment, claims 24 and 36 have been canceled and claims 23 and 35 have been amended. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Rejections under 35 U.S.C. § 112, first paragraph (Written Description)

Claims 23-24 and 35-36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicants, at the time the application was filed, had possession of the claimed invention. According to the Examiner, the claimed invention encompasses a method for detecting prostate cancer or determining expression of SEQ ID NO: 110 in a sample using at least two oligonucleotides which allegedly have unknown structure other than sharing at least 10 contiguous nucleotides in common with nucleotides 1341-2694 of SEQ ID NO: 110, such as "oligonucleotides with 100 nucleotides having 10 nucleotides in the middle in common with nucleotide residues 1341-2694 of SEQ ID NO: 110, which would be expected to hybridize to a whole universe of nucleic acid species, including those that have little or no structural identity with SEQ ID NO: 110." (Page 3, Office Action dated March 5, 2004).

Applicants respectfully traverse this rejection.

The claimed invention is drawn to a method for detecting the presence of prostate cancer or determining expression of SEQ ID NO: 110 in a biological sample using a polymerase chain reaction (PCR), wherein the oligonucleotide primers used in the polymerase chain reaction are specific for residues 1341-2694 of SEQ ID NO: 110 and complements thereof, and then detecting in the sample an expressed polynucleotide sequence that amplifies in the presence of the oligonucleotide primers. The claimed invention is quite clear in its requirement that the oligonucleotide primers used in the recited method must have specificity for SEQ ID NO: 110 in

the context of a polymerase chain reaction. The skilled artisan would therefore understand that oligonucleotide primers used in the claimed methods could not include, as asserted by the Examiner, oligonucleotides with 100 nucleotides having only 10 nucleotides in the middle in common with nucleotide residues 1341-2694 of SEQ ID NO: 110, or oligonucleotides that have little or no structural identity with SEQ ID NO: 110, when such sequences would be understood to be neither specific for SEQ ID NO: 110, nor be expected to amplify an expressed sequence of SEQ ID NO: 110 in the presence of the oligonucleotides. In this regard, the Examiner's position improperly disregards the level of skill and knowledge in the art to which this invention pertains when considering the question of possession under 35 U.S.C. § 112, first paragraph. Rather, it would be understood, when considering this claimed invention as a whole, that the oligonucleotides used in the recited method cannot simply be any sequence which contains at least 10 nucleotides in common with SEQ ID NO: 110, while having completely unlimited and structurally unrelated flanking sequences to the at least 10 contiguous nucleotides. By its very nature, the claimed invention would be understood to place implicit constraints on the oligonucleotides which may be used by requiring that the olignucleotides retain specificity for SEQ ID NO: 110 in a polymerase chain reaction. Furthermore, the extent of such constraints would be readily understood based upon fundamental and well established principles relating to the design and use of olignucleotide primers in PCR amplification methods. Further still, when considered in this light, the skilled artisan would appreciate that the full scope of olignucleotide primers according to the currently claimed invention was squarely within Applicants' possession at the time this case was originally filed.

Without acquiescing to the stated grounds for rejection, and without prejudice to the prosecution of subject matter modified and/or removed by the above amendment, Applicants have amended claims 23 and 35 such that "the oligonucleotide primers consist of at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO:110."

Reconsideration of the Examiner's rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph (Enablement)

Claims 23-24 and 35-36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the Examiner, the specification, while being enabling for a method of detecting prostate cancer or determining expression of SEQ ID NO: 110 in a sample, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO: 110, wherein the oligonucleotide primers consist of at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO: 110, or full length complete complements of nucleotide residues 1341-2694 of SEQ ID NO: 110, does not reasonably provide enablement for a method for detecting prostate cancer or determining expression of SEQ ID NO: 110 in a sample of blood or semen, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO: 110, wherein the oligonucleotide primers comprise at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO: 110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO: 110.

Applicants respectfully traverse this rejection.

It is entirely routine to design oligonucleotide primers comprising at least 10 contiguous nucleotides of SEQ ID NO: 110 which would be expected to have sufficient specificity for SEQ ID NO: 110 to be capable of amplifying an expressed polynucleotide of SEQ ID NO: 110 in a polymerase chain reaction. A certain extent of base pair mismatching between an oligonucleotide derived from SEQ ID NO: 110 and SEQ ID NO: 110 itself may be present flanking the required 10 contiguous nucleotides in common while still retaining specificity for amplifying an expressed polynucleotide of SEQ ID NO: 110. Put another way, oligonucleotide primers need not have complete identity to the regions of SEQ ID NO: 110 from which they are derived, because it is well known and established that oligonucleotide primers can tolerate some degree of base pair mismatching without compromising their ability to hybridize to a target sequence and amplify a desired PCR product. Moreover, the skilled individual would

understand and appreciate, based upon fundamental and well established principles relating to the design and use of olignucleotide primer in PCR amplification methods, how to make and use oligonucleotide primers comprising at least 10 contiguous nucleotides of SEQ ID NO: 110 which would be expected to retain specificity for amplifying an expressed polynucleotide of SEQ ID NO: 110 in a polymerase chain reaction. Applicants respectfully submit that the skilled individual could carry out these claimed methods without undue experimentation and with a reasonable expectation of success.

Without acquiescing to the stated grounds for rejection, and without prejudice to the prosecution of subject matter modified and/or removed by the above amendment, Applicants have amended claims 23 and 35 such that "the oligonucleotide primers consist of at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO:110."

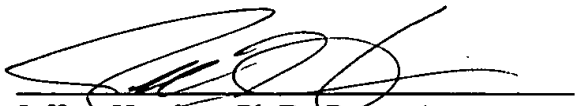
Reconsideration of the Examiner's rejection is respectfully requested.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration is respectfully requested.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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